

PACKAGE LEAFLET

Package leaflet: Information for the user

Expudyne Rx 750mg/5ml oral solution
Carbocisteine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Carbocisteine «sugar-free» 750mg/5ml oral solution is and what it is used for

This medicine thins bronchial secretions (mucus) and makes them easier to cough up. This medicine is for adults and adolescents aged over 15 years only.

It is used for patients with the breathing passages (respiratory tract). These problems happen when too much mucus is made or the mucus is too sticky.

2. What you need to know before you take Carbocisteine «sugar-free» 750mg/5ml oral solution

Do not take Carbocisteine «sugar-free» 750mg/5ml oral solution:

- If you are allergic (hypersensitive) to carbocisteine or any of the other ingredients of this medicine (especially methyl parahydroxybenzoate) listed in section 6.
- If you suffer from peptic ulcers (stomach or gut ulcers).

Warnings and precautions

You must not use medicines which suppress the cough (cough suppressants) or which dry out bronchial secretions when taking Carbocisteine «sugar-free» 750mg/5ml oral solution. This is because Carbocisteine «sugar-free» 750mg/5ml oral solution thins secretions, making them easier to cough up. Coughing is a useful mechanism for expectoration.

Talk to your doctor or pharmacist or nurse before taking Carbocisteine «sugar-free» 750mg/5ml oral solution:

- If you have a fever or are coughing up "greenish" mucus.

- If you have chronic bronchial or pulmonary disease.
- If you have an ulcer in your stomach or gut.
- If you have a gastroduodenal ulcer (affecting the stomach or intestine).
- If you are elderly.
- If you are also taking medicines that are likely to cause bleeding in the stomach or intestine.

Treatment should be stopped if bleeding in the stomach or intestine occurs.

Children and adolescents

Do not give Carbocisteine sugar-free oral solution to children younger than 15 years of age.

Other medicines and Carbocisteine «sugar-free» 750mg/5ml oral solution

This medicine contains carbocisteine. Other medicines also contain this substance. Do not combine them, so as not to exceed the maximum recommended dose.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Carbocisteine «sugar-free» 750mg/5ml oral solution with food and drink

This product should not be mixed with any food and/or drinks.

Pregnancy and breast-feeding

Tell your doctor before taking this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Pregnancy

This medicine should only be used during pregnancy on your doctor's advice.

If you discover that you are pregnant during treatment, talk to your doctor. Only your doctor can decide whether it is necessary to continue treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Breastfeeding

You may breastfeed your child while taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No effects were seen on the ability to drive and use machines.

Important information about some of the ingredients of Carbocisteine sugar-free oral solution.

This medicine contains:

- **sodium:** 96.1mg (4.2mmol) of sodium per 5ml dose. This medicine contains 96.1mg in each dose. This is equivalent to 4.8% of the recommended maximum daily dietary intake of sodium for an adult.
- **sodium methyl parahydroxybenzoate:** 7.5mg per 5ml dose. it may cause allergic reactions (possible delayed)..

3. How to take Carbocisteine «sugar-free» 750mg/5ml oral solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- For oral use only. Take this medicine by mouth.
- Use the measuring cup provided.
- Shake the bottle before use.

Adults including the elderly and children from 15 years of age

The initial dose is 5ml three times a day; if symptoms improve, your doctor may lower your dose to 5ml, 2 times a day. The maximum daily dose is 15ml.

Children under 15 years

Not recommended.

Check the dose carefully

The amount of oral solution needed to provide the required dose is less than for other carbocisteine products.

If you take more Carbocisteine «sugar-free» 750mg/5ml oral solution than you should

- If you take more Carbocisteine «sugar-free» oral solution than the label states or your doctor has prescribed, or if you think a child has accidentally swallowed any, contact the nearest hospital casualty department or a doctor for advice **immediately**.
- If you take too much Carbocisteine «sugar-free» oral solution you may get an upset stomach (gastrointestinal disturbance).
- Take this leaflet with you.

If you forget to take Carbocisteine «sugar-free» 750mg/5ml oral solution

If you forget a dose, take the next dose as soon as you remember.
Do not take a double dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Carbocisteine «sugar-free» 750mg/5ml oral solution immediately and see a doctor or go to hospital straightaway if:

- You have an allergic reaction. Signs of an allergic reaction include: a rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.
- You have blistering or bleeding of the skin, including around your lips, eyes, mouth, nose and genitals. You may have flu-like symptoms and fever. This may be something called “Stevens-Johnson syndrome”.
- You have blood in your vomit or black tarry stools.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea
- Stomach pain
- Headache
- Skin rash

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbocisteine «sugar-free» 750mg/5ml oral solution

Do not store above 25°C.

Keep this medicine out of the sight and reach of children.

Wash and dry the measuring cup after use.

Once opened use within one month.

Do not use this medicine after the expiry date which is stated on the carton and label after “EXP”. The expiry date refers to the last day of that month.

Do not dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Carbocisteine «sugar-free» 750mg/5ml oral solution contains

- each 5ml of oral solution contains 750mg of the active substance carbocisteine.
- The other ingredients are: Glycerol (E 422), Saccharin sodium (E 954), Hydroxyethylcellulose (E 1525), Xanthan gum (E 145), Caramel powder, Raspberry flavour, Sodium Methyl Parahydroxybenzoate (E 219), sodium hydroxide (E 524) and purified water.

What Carbocisteine «sugar-free» oral solution looks like and contents of the pack

Carbocisteine «sugar-free» 750mg/5ml oral solution is clear, amber-coloured liquid, with raspberry odour.

Carbocisteine «sugar-free» 750mg/5ml oral solution is packed in 100ml or 200ml glass bottles and with child resistant (HDPE) screw cap. It comes with a measuring cup with 2.5 and 5 ml graduations.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland:

Luxembourg:

Malta:

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